IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of	Confirmation No. 1632
BRANCACCIO et al.	Atty. Ref.: 4636-25
Appln. No. 10/538,736	T.C. / Art Unit: 1632
Filed: August 11, 2005	Examiner: J. Hama

FOR: MELUSIN, A MUSCLE SPECIFIC PROTEIN, AS A DRUG TARGET FOR PREVENTION AND TREATMENT OF HEART FAILURE

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PETITION UNDER 37 CFR §§ 1.144 AND 1.181

June 27, 2007

Mail Stop Petition
Hon. Commissioner of Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Applicants petition the Director to invoke his supervisory authority and to review the Examiner's final restriction requirement. In accordance with M.P.E.P. § 1002.02(c), it is understood that authority to decide this petition may be delegated to a Technology Center Director.

The fee for this petition is attached. If the fee is missing or deficient, authority is given to charge any deficiency in the fee which should have been filed herewith to our Account No. 14-1140 under Order No. 4636-25.

ISSUE IS RIPE FOR REVIEW

The Examiner required restriction of pending claims 1-25 and 40-42 in the Office Action mailed October 23, 2006. Applicants traversed the requirement in their response filed December 18, 2006.

The restriction requirement was made final in the Office Action mailed March 27, 2007.

It is respectfully requested that the Director invoke his supervisory authority and review the Examiner's restriction requirement so that all of claims 1-25 and 40-42 are examined in this patent application.

This petition is timely because the restriction requirement was made final and an appeal has not yet been filed in this patent application.

STATEMENT OF FACTS AND POINT(S) TO BE REVIEWED

This patent application was filed under 35 U.S.C. § 371 as a U.S. national stage of Int'l Appln. No. PCT/IT02/00807. The Examiner's restriction requirement is reviewed under "unity of invention" practice in accordance with PCT Rule 13.

After a first restriction requirement, Applicants elected with traverse Group 1 (i.e., claims 1-17 and 20-22) drawn to nonhuman transgenic animals having altered melusin expression, and cells therefrom. It was argued as part of the traversal that the claims of Groups 2 and 4 should also be examined. In the first Office Action mailed May 3, 2006, the Examiner was persuaded by this argument and claims 1-25 were examined on the merits. Applicants responded on July 27, 2006 to the first Office Action and also added claims 40-42, which are directed to the elected invention.

In the Office Action mailed October 23, 2006, the Examiner required restriction of claims 1-25 and 40-42 (i.e., the second restriction requirement). In response, Applicants elected with traverse Group 2 (i.e., claims 1-18, 24-25 and 40-42) drawn to nonhuman transgenic animals comprising a decrease in the level of melusin expression, methods of screening compounds for pharmacological activity using such animals, and methods of making such animals at page 2 of the Action. In a further restriction requirement the Examiner required election of (i) stable or transient modification and (ii) one or three genetic approaches at pages 5-6 of the Action. Applicants elected stable modification and homologous recombination. It is undisputed that the subject matter of all the claims pending on October 23, 2006 had already been searched and examined in the Office Action mailed May 3, 2006. Claims 1-25 and 40-42 are linked by the general inventive concept of a nonhuman transgenic animal having altered melusin expression. Melusin prevents cardiac dilation and heart failure.

Applicants disagree with the Examiner's allegation that the pending claims lack unity of invention, and therefore belong to different groups of inventions. Applicants agree that the inventions indicated by the Examiner are separately patentable. But traversal is based on the pending claims being so linked as to form a single general inventive concept under PCT Rule 13.1.

The Examiner alleged that the claims do not relate to a single general inventive concept because they lack the same special technical feature under PCT Rule 13.2. But here, the special technical feature linking the pending claims is that they all involve "a non-human transgenic animal having altered melusin expression" (note that the cells of claims 20-23 are derivable from that animal), which relates to the biological function of the melusin gene in such animals instead of the identification of the melusin gene itself. Since the pending claim rejections do not allege any of the claims are anticipated or obvious, there is no evidence that this special technical feature is found in the prior art.

Applicants discovered that melusin prevents cardiac dilation and heart failure. For this reason, they disagree with the Examiner's holding the claims of Groups 1, 3, 5 as distinct inventions from the claims of Groups 2, 4, 6 since decreasing or increasing melusin expression in a nonhuman transgenic animal are different uses of the same inventive concept (i.e., altering melusin expression). In particular, decreased melusin expression can be useful to generate heart failure animals or in vitro cellular models to test medicaments useful as therapeutic agents. On the other hand, increased melusin level can provide a treatment for heart failure. This general inventive concept links all of the pending claims. Accordingly, Applicants submit that there is no lack of unity with regard to the pending claims.

Moreover, the generic or linking claims in this patent application include both "an increase" and "a decrease" as alterations in melusin expression. The alterations may be caused by a "stable" or "transient" modification. Additionally, these generic or linking claims also include different genetic approaches for altering melusin expression, the level at which melusin expression is controlled, the methods of inducing a hypertensive condition, and the strains of mice.

At page 2 of the Office Action mailed October 23, 2006, the Examiner alleged the first restriction requirement was incorrect and "a proper search and examination cannot be carried out" on the pending claims. But this allegation contradicts the instruction to examiners in M.P.E.P. § 704.01 that "full faith and credit should be given to the search and action of the previous examiner unless there is a clear error in the previous action or knowledge of other prior art." Here, no evidence of either clear error or knowledge of other prior art was provided. Even assuming arguendo that multiple distinct inventions are claimed in this patent application, restriction is discretionary because a patent may contain such claims (see 35 U.S.C. 121 "The validity of a patent shall not be questioned for failure of the Director to require the application to be restricted to one invention"). Therefore, the absence of a requirement to restrict among claims 1-25 and 40-42 is not clear error in the first restriction requirement. The full faith and credit that should be given to the previous examiner's search prohibits restriction of subject matter that has already been searched and examined in a previous Office Action on the merits.

Finally, after the examination of the elected invention in the Office Action mailed May 3, 2006, there is clearly no serious burden to search claims 1-25 and 40-42 in this patent application. In spite of the Examiner's protestations on pages 4-7 of the Office Action mailed October 23, 2006 that their examination would be burdensome, she did not provide any evidence that the previous examination was deficient or improper.

ACTION REQUESTED

As discussed above, Applicants submit that all of claims 1-25 and 40-42 share a special technical feature. Therefore, having satisfied the "unity of invention" requirement of PCT Rule 13, all of the pending claims should be examined in this U.S. national stage application. Furthermore, no serious burden was demonstrated that prevents continued prosecution of this patent application according to the first restriction requirement.

The Director is requested to invoke his supervisory authority over the Examiner's actions, withdraw the second restriction requirement, and reinstate the first restriction requirement so that claims 1-25 and 40-42 are examined in this patent application.

Applicants earnestly solicit grant of this petition. If any further information would assist in this decision, the Director or his designee is invited to contact the undersigned.

Respectfully submitted,

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By: _____

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